REMARKS/ARGUMENTS

Upon careful and complete consideration of the Office Action dated January 31, 2006, applicants have amended the claims which, when considered in conjunction with the comments herein below, are deemed to place the present application into condition for allowance. Favorable reconsideration of this application, as amended, is respectfully solicited.

The Office Action rejected Claims 1-3, 5-7, 9-15 and 17 under 35 U.S.C. §102(b), as allegedly being anticipated by U.S. Patent No. 4,902,718 to Bayless et al. (hereinafter referred to as "Bayless et al.").

As indicated by the Examiner, the present invention relates to methods of maintaining normal blood pressure, treating hypertension and reducing blood pressure using glycine betaine. The Office Action has cited Bayless et al. for teaching a method of treating a condition of hypertension by administering a combination of calcium agent, methionine compound and betaine. The amount of betaine used by Bayless et al. falls within the ranges as claimed in present claims 11-15. As hypertension is a common disorder in which blood pressure remains abnormally high, the Office Action concludes that the treatment of hypertension by Bayless et al. would necessarily result in both the reduction of high blood pressure and normalization of blood pressure. Consequently, the Office Action concludes that Bayless et al. teaches each claimed method of the present invention.

The Examiner has noted, however, that Bayless et al. teach the use of a combination of agents, i.e. a combination of calcium agent, methionine compound and betaine. It was further noted by the Examiner that the independent method claims of the present invention while reciting only the use of glycine betaine, are open-ended in the use of the word

"comprising" and thus made the conclusion that the claimed invention was anticipated by Bayless et al.

The applicants have accordingly amended the independent claims, i.e. claims 1, 5 and 10 to recite methods "consisting essentially of" administering glycine betaine. As amended, applicants' have restricted the claimed invention to the administration of the specified glycine betaine, as well as those materials that do not materially affect the basic and novel characteristics of the claimed invention. Accordingly, the amended claim would allow for the glycine betaine to be administered in various forms or products as indicated in the subject specification, i.e. such as a pharmaceutical product, a food product, a food supplement, a dietary supplement or a natural product. What the amendment does accomplish is the restriction of the product to be administered from including other material ingredients such as those required by Bayless et al. Again, Bayless et al. teach treating a condition of hypertension by administering a combination of calcium agent, methionine compound and betaine. Clearly, the claimed invention as newly amended could not include either the calcium agent or the methionine compound. Based on the amended claims, it is respectfully submitted that the reference no longer meets the claimed limitations of the present invention.

It is respectfully submitted that it is axiomatic that anticipation under Section 102 requires that the prior art reference disclose every element of the claim. In re King, 801 F.2d 1324, 1326, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986). Thus, there may be no differences between the subject matter of the claim and the disclosure of the prior art reference. Stated in another way, the reference must contain within its four corners adequate directions to practice the invention. The corollary of this rule is equally applicable. The absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1571, 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986).

The essential features of the cited method involve administering a combination of calcium agent, methionine compound and betaine. The methods in accordance with the present invention relate to administering glycine betaine as the sole effective ingredient. Bayless et al. do not in any way teach, refer or suggest treatment with the administration of only betaine. Stated in another way, the skilled artisan reading Bayless et al. would not attempt the claimed invention without the inclusion of the other taught ingredients, i.e. the calcium agent and methionine compound. Consequently, the rejection of the claims under 35 U.S.C. §102(b) must fall in accordance with King and Kloster Speedsteel.

Based on the arguments submitted above, it is respectfully requested that the 102 (b) rejections of claims 1-3, 5-7, 9-15 and 17 based on Bayless et al. be withdrawn.

The Office Action next rejected claims 1-17 under 35 U.S.C. §102(b) as allegedly anticipated by ZA 9503838 to Davis et al. (hereinafter referred to as "Davis et al.").

The analysis of this rejection is identical to the earlier rejection based on Bayless et al. That is, the Office Action has cited Davis et al. for teaching a method involving the administering of a combination of betaine hydrochloride and $MgCO_3$. Again, as originally drafted, the independent claims of the present application did not preclude the additional elements as taught and required by the cited reference. As amended, with the use of the "consisting essentially of" language, applicants have effectively restricted the claimed methods from "unrecited elements" that would materially affect the basic and novel characteristics of the claimed invention. Clearly, Davis et al. requires that $MgCO_3$ be used in combination with the betaine, while the present invention as now claimed excludes the possible use of said compound. As such, Davis et al. can no longer be seen as anticipating the claimed invention and the rejection of the claims based on Davis et al. should therefore be withdrawn as well.

Finally, it is further submitted that all the claims in the application as presently submitted contain patentable subject matter and a Notice of Allowance is earnestly solicited.

Respectfully submitted,

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